STERIS®

K073683

510(k) Summary
For
Verify® Challenge Packs – Version 2 -

JAN 25 2008

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Submission Date: December 26, 2007

1. Device Name

Indicator Pack Models:	Verify® 270F 4 Challenge Pack Verify® 275F 3 Challenge Pack
Common Name:	Chemical Indicator
Classification Name:	Physical/chemical sterilization process indicator (21 CFR 880.2800 (b), Product Code JOJ).

2. Predicate Devices

- Verify® Challenge Packs - K070895.
- Modified Browne Packaging and Label Steam Process Indicator – K032801.

3. Device Description

The proposed Verify® Challenge Packs – Version 2 -consist of an emulating indicator surrounded by a steam penetration barrier. The indicator ink inside the proposed Verify® Challenge Packs changes from yellow to blue/purple color when the steam sterilization cycle is complete:

- The Verify® 270F 4 Challenge Pack –Version 2 - can be used to monitor a 4 minute 270°F/132°C Steam-Flush Pressure-Pulse (SFPP) and pre-vacuum steam sterilization cycle.

- The Verify® 275F 3 Challenge Pack – Version 2 - can be used to monitor a 3 minute 275°F/135°C pre-vacuum steam sterilization cycle.

The process indicator outside of the packs undergoes a visual color change from pink to dark purple when exposed to steam in a temperature range of 250°F (121°C) to 275°F (135°C).

4. Intended Use

The Verify® Challenge Packs –Version 2- are chemical indicator test packs intended for use by health care providers to accompany products being sterilized through a sterilization procedure. The indicator sheet within the challenge pack changes color from yellow to blue/purple when exposed to the proper time and temperature of the designated steam sterilization cycle. The performance of the Verify® Challenge Packs – Version 2 - meets the requirements of ANSI/AAMI / ISO 11140-1:2005 for emulating [Class 6] steam indicators.

The process indicator printed outside of the packs undergoes a visual color change from pink to dark purple when exposed to steam in a temperature range of 250°F (121°C) to 275°F (135°C).

5. Description of Safety and Substantial Equivalence

The proposed and predicate devices are all single use indicator test packs for use in steam sterilization cycles. The differences between the proposed Verify® Challenge Packs – Version 2 - and the predicate device Verify® Challenge Packs described in K070895 are limited to the presence of an outside pack process indicator identical to the predicate device described in K032801. There are no differences in design, materials, and parameters of the sterilization cycles these indicator test packs are designed to monitor. The addition of the process indicator to the outside of the challenge packs does not raise any new issues of safety and efficacy.

6. Verification and Validation Activities

A risk analysis and the necessary verification and validation activities were performed to demonstrate that the design outputs of the modified device meet the design input requirements.

Performance testing was conducted to verify that the process indicator on the outside of the challenge packs change color from pink to dark purple when exposed to the following full steam sterilization cycles.

- 4 minute 270°F/132°C dynamic air removal steam sterilization cycle.
- 3 minute 275°F/135°C dynamic air removal steam sterilization cycle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2008

Mr. John Scoville
Fellow, Regulatory Affairs Sterilization Technology
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060-1834

Re: K073683
Trade/Device Name: Verify® Challenge Packs - Versions 2 -
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: December 26, 2007
Received: December 28, 2007

Dear Mr. Scoville:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Verify® Challenge Packs – Version 2 -

Indications For Use:

The Verify® Challenge Packs –Version 2 - are test packs consisting of an emulating indicator surrounded by a steam penetration barrier, intended for use in steam sterilization. The Verify® Challenge Packs indicators change color from yellow to blue/purple when exposed to the appropriate cycle temperature, type, and duration. The challenge pack models and their cycle temperatures, types, and times are:

MODEL	TEMPERATURE	STERILIZATION TYPE	TIME
Verify® 270F 4	270°F (132°C)	Pre-vacuum, Steam Flush Pressure Pulse (SFPP)	4 minutes
Verify® 275F 3	275°F (135°C)	Pre-vacuum	3 minutes

There is a process indicator outside of the packs which undergoes a visual color change when exposed to steam in a temperature range of 250°F (121°C) to 275°F (135°C).

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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